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VA HIV REPORT

Department of Veterans Affairs

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Note from the Program Office: HIV Research in VA

This issue of the *VA HIV Report* highlights the importance of research in VA's mission. The VA provides a rich environment in which to conduct many aspects of research related to HIV infection.

The Center for Public Health Research Resources (CPHRR) is part of the Public Health Strategic Health Care Group (PHSHG) and was established to stimulate and foster research opportunities that increase knowledge and improve the quality of care for HIV-infected veterans. The CPHRR staff has extensive experience in areas such as research design, regulatory affairs, and clinical trial management. Staff members meet regularly with representatives of the pharmaceutical and medical diagnostics industry to learn about new research opportunities.

The CPHRR website (http://vaww.va.gov/chrr/) provides VA investigators with information about research opportunities, regulatory affairs, and lists peer-reviewed publications authored by VA investigators. A new feature coming soon will be a web board, in which investigators can discuss research questions or projects and catalyze new collaborative projects.

The CPHRR, in cooperation with the Center for Quality Management in Public Health (CQM), is also responsible for the administration of research projects using the Immunology Case Registry (ICR). The ICR presents an excellent source of HIV-related information that can be used to answer many hypothesis-driven questions. More information about the CQM is available on the PHSHG website (http://vaww.vhaco.va.gov/phshcg/cqm/TOC.htm).

Mark Holodniy MD
Director, Center for Public Health Research Resources

Inside:

Veterans Aging Cohort Study (VACS)

The Veterans Aging Cohort Study (VACS) is a prospective, observational cohort study of HIV infected veterans who are group-matched for age, race and site of VA care. The study's main goal is to understand the role of co-existing medical and psychiatric disease in determining the clinical outcomes of HIV infection. VACS is particularly focused on the role of alcohol use and abuse in determining health outcomes. VACS is funded primarily by the National Institute on Alcoholism and Alcohol Abuse (NIAAA), of the National Institutes of Health.

VACS PI Amy Justice (lower right) reviews laboratory reports with colleagues Shawn Fultz (seated), Kristina Crothers, and Scott Braithwaite.

VACS consists of two concurrent, ongoing projects. The first is a "virtual cohort" based on administrative data of over 25,000 HIV infected veterans and a similar number of HIV negative controls. The "virtual cohort" is used to understand the overall impact of HIV infection and comorbid conditions on survival and health care utilization. Recently this cohort has been supplemented with data from the Immunology Case Registry and from the Pharmacy Benefits Management Package. Thus the data now includes full pharmacy data on all the patients in the cohort and laboratory data on HIV positive subjects.

The virtual cohort is enhanced and validated by a prospectively assembled cohort of veterans with and without HIV infection, in care at 8 VA medical centers

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OPTIMA–VA Leads Tri-National Study of HIV Treatment Strategies

Options in Management with Anti-Retrovirals (OPTIMA) is the first clinical trial conducted by the Tri-National Trials collaborative, which involves the US Department of Veterans Affairs (VA), the United Kingdom Medical Research Council, and the Canadian Institute for Health Research. OPTIMA compares management strategies for patients with advanced AIDS who are no longer experiencing adequate suppression of viral replication while on highly active antiretroviral therapy (HAART) and who have few or no treatment options due to anti-retroviral (ARV) drug resistance or intolerance. Patients are randomized first to a 3-month ARV drug free period or no interruption, followed by a second randomization to optimized Standard-HAART (a regimen of 4 or fewer ARV's) versus Mega-HAART (a regimen of 5 or more ARV's). The study evaluates the effect of these various management strategies on mortality and progression of HIV disease, frequency of serious adverse events, quality of life, and health economic consequences.

OPTIMA began recruitment in July 2001 and anticipates continued enrollment

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Reports from the Immunology Case Registry

National Trends in Antiretroviral (ARV) Drug Use

	FY1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004
Number of patients on any ARV nationally									
Any ARV	9607	11934	12805	13537	14014	14513	14888	15117	15623
Number of patients on each class of ARV									
Any nRTI	9532	11885	12695	13422	13871	14337	14716	14969	15459
Any nnRTI	19	1025	2695	5077	6481	6956	7161	7520	7791
Any PI	2611	8024	10381	10675	9999	9528	9101	8558	8979
Number of patients on each ARV									
ABACAVIR			1	1341	2159	2401	2332	2286	2171
ABACAVIR/LAMIVUDINE/ZIDOVUDINE						558	1476	1817	1726
AMPRENAVIR				448	1034	1041	777	564	373
ATAZANAVIR								335	1998
DELAVIRDINE	1	166	483	302	180	166	151	129	105
DIDANOSINE	1929	2238	2651	2925	2705	2745	2787	2669	2518
EFAVIRENZ			43	2802	4123	4553	4778	5223	5613
EMTRICITABINE								19	233
ENFUVIRTIDE								135	275
INDINAVIR	1776	6035	5538	4461	3820	3178	2471	1810	1340
LAMIVUDINE	6511	10806	10091	7092	6296	5940	5844	5988	6111
LAMIVUDINE/ZIDOVUDINE			3425	5261	5955	6124	5751	5366	5555
LOPINAVIR/RITONAVIR					6	1665	2815	3614	3965
NELFINAVIR		1895	4822	5461	4643	3900	3284	2637	2036
NEVIRAPINE	18	889	2291	2549	2528	2516	2480	2416	2322
RITONAVIR	287	879	1694	1813	2521	2448	1853	1581	2468
SAQUINAVIR	988	1843	2439	2260	1854	1289	935	845	668
STAVUDINE	2656	6004	7181	7392	7225	7067	6387	5176	4066
TENOFOVIR							1814	4158	5644
ZALCITABINE	1478	878	569	377	240	155	106	83	61
ZIDOVUDINE	6902	8000	5333	1840	1077	845	748	714	689

DATA SOURCE: Immunology Case Registry, data through October 2004. Antiretrovirals received as part of a research study and those labeled as investigational drugs are not included.

Inpatient Care

	FY 2003	FY 2004
Inpatient discharges	8646	8829
Patients with inpatient discharges	4575	4633
Mean length of stay (LOS) in days	15.7	14.6
Median LOS	6	6
Discharges with LOS of the following duration:		
1 day	255	242
2-3 days	2069	2058
4-7 days	2674	2908
8-14 days	1802	1872
>14 days	1846	1749

LOS (length of stay) = discharge date minus admit date + 1. Other sources of VA data may calculate LOS differently. LOS is calculated for all types of inpatient facilities, including acute and long term care hospitals, nursing homes and domiciliary facilties. DATA SOURCE: Immunology Case Registry, data through October 2004.

Patients Added to ICR*

	FY 2003	FY 2004
Female	42	61
Male	1901	2384
Unknown	0	7
TOTAL	**1943**	**2452**
American Indian/Alaskan native	4	9
Asian/Pacific Islander	2	8
Black (Not Hispanic)	785	892
Hispanic	119	97
Mixed Race	17	1
Unknown	382	758
White (Not Hispanic)	634	687

* Those for whom the date of first transmission of a record was during the given time period. DATA SOURCE: Immunology Case Registry, data through October 2004.

Selected Immunology Case Registry Data on Demographics of Patients in Care

	Patients in care	Sex*		Race/Ethnicity				
	Total	Male	Female	Black (Not Hispanic)	Hispanic	White	Unknown	All other
FY 2002	20035	19530	502	9501	1486	7061	1152	835
FY2003	20548	20045	500	9455	1477	7210	1546	860
FY2004	20518	20009	505	9328	1428	7177	1745	839

* 3 patients in FY02, FY03, and 4 in FY04 were missing sex data or were designated unknown or both male and female.
DATA SOURCE: Immunology Case Registry, data through October 2004.

Selected Immunology Case Registry Data by VISN

VISN#	VISN Name	Patients in care		Deaths		All CD4<200*	
		FY 2003	FY 2004	FY2003	FY2004	FY2003	FY2004
1	New England Healthcare System	593	578	38	25	118	108
2	Healthcare Network Upstate New York	259	238	15	16	50	38
3	NY/NJ Veterans Healthcare Network	2112	2004	120	105	406	350
4	Stars & Stripes Heathcare Network	923	894	55	52	199	193
5	Capitol Health Care Network	1441	1413	73	73	279	291
6	Mid-Atlantic Health Care Network	1220	1240	68	82	301	283
7	Atlanta Network	1949	1990	95	94	388	382
8	Sunshine Healthcare Network	2604	2706	148	145	451	450
9	Mid South Healthcare Network	581	555	44	42	147	122
10	Healthcare System of Ohio	494	482	13	18	102	99
11	Veterans in Partnership	690	699	36	39	114	98
12	Great Lakes Health Care System	716	717	37	37	152	126
15	Heartland Network	469	438	30	25	93	83
16	South Central VA Health Care Network	1839	1855	100	90	405	389
17	Heart of Texas Health Care Network	952	916	37	46	162	153
18	Southwest Health Care Network	588	603	38	45	135	121
19	Rocky Mountain Network	333	349	25	15	59	67
20	Northwest Network	577	585	34	27	107	97
21	Sierra Pacific Network	1085	1024	66	47	183	154
22	Desert Pacific Healthcare Network	1841	1838	75	67	317	291
23	Midwest Health Care Network	263	248	17	13	48	44

DATA SOURCE: Immunology Case Registry, data through October 2004

*Patients whose quantitative CD4 lymphocyte counts were all less than 200 cells/mm^3 during the time period

The Immunology Case Registry is VA's database of veterans infected with HIV receiving care in VA facilities. Data are collected directly from the electronic medical records of all patients entered into the registry by local facilities. For more information on the ICR, visit the Web site of the Center for Quality Management in Public Health: http://vaww.vhaco.va.gov/phshcq/cqm/TOC.htm

VACS

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around the country. Subjects in the prospective cohort have provided consent to allow access to detailed medical record information, and subjects as well as their clinicians provide additional data through surveys and interviews. In addition to information from the medical record, survey and interviews, VACS includes a specimen bank with samples of serum, plasma, and blood pellets. This permits VACS investigators to explore in more detail the associations observed in the "virtual cohort" and to better understand what are likely to be complex and overlapping factors resulting in differences of health care utilization and clinical outcomes. Enrollment at the 8 VACS sites have already exceeded the original target of 6,090 veterans.

The VACS study team is proud of its many ongoing collaborative studies both within and outside the VA system and welcomes proposals for analyses and substudies.

VACS: Veterans Aging Cohort Study
Principal Investigator: Amy Justice, MD, MPH, PhD
Site PIs; David Rimland(Atlanta), Kris Ann Oursler (Baltimore), Sheldon Brown (Bronx), Maria Rodriguez-Barradas (Houston), Matthew Goetz (Los Angeles), Michael Simberkoff (New York Harbor), Adeel Butt (Pittsburgh), Cynthia Gibert (Washington DC)
For more information: Refer to the VACS Website: http://www.vacohort.org/ or contact Beth Dombrowski, VACS Coordinator, at 203.932.5711 ext. 5371; email: Elizabeth.Dombrowski@med.va.gov.

QUERI-HIV Works to Improve Care Quality for HIV-Infected Veterans

In 1998, the VA created the Quality Enhancement Research Initiative, or QUERI, in an attempt to overcome the long delays in integrating research evidence into routine practice. Eight QUERI Coordinating Centers each focus on a different disease or condition selected because of high prevalence or high burden among veterans, their families, and the VA health care system. The QUERI-HIV Coordinating Center is located at the VAMC in San Diego, with affiliated investigators throughout the VA system. Their mission is to ensure better health for veterans living with HIV by making evidence-based HIV care more accessible, optimizing the application of evidence-based HIV therapies, and improving the delivery of collaborative and comprehensive treatment of co-morbid conditions. QUERI-HIV has been involved in developing databases, conducting surveys of HIV providers and patients, and studying the use of clinical reminders and care collaboratives to improve HIV management. Current and future research priorities encompass three broad areas: improving access to HIV care, optimizing HIV drug therapy, and improving treatment of co-morbid conditions.

Some specific projects that are planned or currently underway include:

- A study of the impact of a nurse-based counseling and rapid test intervention to improve early diagnosis of HIV infection
- A computer-based survey tool to help providers collect accurate information about adherence from patients
- Studies of the relationship between various classes of HAART and hospitalization or mortality from cardiac or cerebrovascular events.

As an example of QUERI research activities, Douglas Owens and his colleagues from the Palo Alto VA Medical Center conducted a blinded seroprevalence survey using blood samples from over 8,700 patients at six VA facilities. The average infection rate was 3.7%. In a separate study, QUERI investigators found that many VA patients with risk factors for HIV infection had not been tested. These initial studies prompted QUERI investigators to investigate further the strategies that could lead to more effective HIV screening and testing, some of which are described above.

HIV QUERI: Quality Enhancement Research Initiative:
QUERI-HIV leadership includes Allen Gifford, MD, Steven Asch, MD, MPH, Matthew Goetz, MD, and Candice Bowman, PhD, RN.

For more information on HIV QUERI: email Joanna Bone at joanna.bone@med.va.gov or phone her at 858-552-8585 x5954. Watch for the QUERI-HIV website to go live in March '05. The link will be www.hsrd.research.va.gov/queri-hiv.

Policy Corner: Research Using Immunology Case Registry Data

As a VA investigator, how can I use data from the Immunology Case Registry for research?

The national Immunology Case Registry (ICR) is used by the Public Health Strategic Healthcare Group (PHSHG) primarily as a tool for tracking overall trends in HIV-related outcomes and health care utilization for planning and quality improvement purposes. Local ICR data is used primarily for patient care purposes.

Both the local and national-ICR data can be used for research if proper steps are taken to ensure that the information is used in ways that protect patients from loss of privacy and other risks associated with research involving human subjects. For research involving only data from local ICR's the steps are the same as those for research involving review of the electronic medical record. These projects require review and approval by a local Institutional Review Board (IRB) and in some cases these boards may require that individual subjects sign consent forms or authorization for release of protected health information in accordance with HIPPA (Health Insurance Portability and Privacy Act) regulations.

The use of national ICR data for research also requires IRB review and approval, but additional steps must be taken to ensure that the uses of the data are consistent with the responsibilities and priorities of PHSHG as managers of the database. A new, streamlined system for submitting and reviewing applications for use of national ICR data is being developed and will be implemented later in 2005. In the meantime, individual requests for access to ICR data should be directed to the Jude Lopez at the Center for Public Health Research Resources (jude.lopez@med.va.gov).

OPTIMA

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through December 2005 with follow-up through December 2006. Currently, with more than 320 patients enrolled and a median follow-up of more than one year, OPTIMA is the largest study of ARV treatment interruption in this patient group and the only randomized controlled trial of Standard versus Mega-HAART. The 26 participating VA sites are responsible for more than 80% of the recruitment to date.

The VA component of OPTIMA is conducted as Cooperative Studies Protocol 512, coordinated by the West Haven Cooperative Studies Coordinating Center, and co-chaired by investigators at the Bronx and Palo Alto VA medical centers. Through OPTIMA, the VA has helped to develop effective methods for data exchange, logistical coordination, and other procedures for scientific and administrative collaboration that may serve as models for future clinical research collaborations between VA and its international partners.

OPTIMA: Options in Management with Anti-Retrovirals
Protocol Chairs: Sheldon Brown MD and Mark Holodniy MD
For more information: Refer to OPTIMA website (http://www.optimatrialus.org/)